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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,475	09/29/2000	DANIEL RAJOTTE	P-LJ 4377	7437

23601 7590 06/17/2003

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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/676,475	RAJOTTE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Marjorie A. Moran	1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 08 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 5-30 is/are pending in the application.
- 4a) Of the above claim(s) 8-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) 5 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>13</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)               |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> | 6) <input type="checkbox"/> Other: _____  |

***Election/Restrictions***

Applicant's election with traverse of Group I, claims 5-15, and of species SEQ ID NO: 1 in Paper No. 12, filed 4/8/03, is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to search and examine both Groups I and II, and both SEQ ID NO's 1 and 2 (both species of the genus of SEQ ID NO: 17). This is not found persuasive with regard to Groups I and II because the claims are directed to different methods requiring different search, and different consideration with regard to enablement, written description, definiteness, etc. As a search for any single Group requires a search of nonpatent literature and foreign patents as well as US patents, the examiner maintains that it would be an undue burden to search and examine both Groups I and II. With regard to the species election, it is noted that applicant has not traversed the election of group (a) versus group (b). As species (a) and (b) represent entirely different structures, and applicant has not traversed this election, the election is maintained. With regard to the requirement for election of a species within the genus of SEQ ID NO: 17, it was found that SEQ ID NO: 1 was free of the prior art. The search was then extended to other members of the genus; SEQ ID NO: 2 was found to be free of the prior art. Claims directed to the genus of SEQ ID NO: 17 were not found to be allowable for reasons set forth below, therefore the species search was NOT extended to the specie (b).

The requirement for restriction between Groups I and II, and for election between species (a) and (b) is still deemed proper and is therefore made FINAL.

Claims 8-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

An action on the merits of elected claims 5-7, as they read on the species of SEQ ID NO: 17, follows.

#### ***Information Disclosure Statement***

The IDS filed 2/1/01 has been considered in full.

#### ***Specification***

The disclosure is objected to because of the following: pages 123-124 of the specification refer to a Table 1; no Table 1 is found in the application. The description ends on page 150. Tables 2-11 are found on pages 151-163, therefore there do not appear to be any "missing" pages corresponding to Table 1. It is possible that the Tables are misnumbered; however, the description of Table 2 found on pages 123-124 appears to correspond to Table 2 found on page 151. Applicant is advised that any amendment of the specification or claims must be fully supported by the originally filed specification and/or claims in order to avoid the addition of new matter.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for selectively directing a moiety to lung endothelium wherein the moiety is conjugated to SEQ ID NO: 1 or SEQ ID NO: 2, does not reasonably provide enablement for selectively directing a moiety to lung endothelium wherein the moiety is linked to any other "GFE" peptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

The claims are enabled for a method of selectively directing a moiety to lung endothelium wherein the moiety is conjugated to SEQ ID NO: 1 or SEQ ID NO: 2 because the specification teaches that both SEQ ID NO: 1 and SEQ ID NO: 2 are selectively directed to MDP in lung endothelium, but are not enabled for a similar method wherein the moiety is linked to any other GFE peptide, as represented by the genus of SEQ ID NO: 17, because neither the specification nor the prior art teach that the genus of GFE peptides are MDP-homing molecules which are selectively directed to

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lung endothelium. The specification discloses, in working examples, on pages 121-124 and 137-141, that phage displaying SEQ ID NO's 1 and 2, and fusion proteins comprising SEQ ID NO's 1 and 2 home selectively to lung, and that both SEQ ID NO's 1 and 2 bind to MDP, thereby providing enablement for the claimed method using SEQ ID NO's 1 and 2. The specification states on page 123 that peptides containing a GFE motif "predominate" in additional peptide found to bind to lung, but as Table 1 is missing (see above), and page 123 only exemplifies SEQ ID NO's 1 and 2 as the "predominate" peptides, the disclosure of the specification does not provide any support for this statement. The specification, in fact, discloses on page 122 and Table 2 that peptides NOT comprising a GFE motif also home to or are found in lung. It is noted that of all the peptides found in lung that are listed in Table 2, ONLY SEQ ID NO: 1 has a GFE motif. This is NOT evidence that peptides with GFE motifs "predominate" among those peptides which may selectively bind to lung tissue. The state of the art is such that peptides of SEQ ID NO: 17 are known which comprise a GFE motif and are NOT known to "home to" or bind selectively to lung. See ARAP et al. (WO 0220722), who teaches on pages 120-121 that at least two GFE-containing peptides (SEQ ID NO's 250 and 272) are those which target ovarian cancer. As these peptides bind to *ovarian* cancer targets, one skilled in the art would reasonably doubt that they would selectively home to lung endothelium. ARAP does not teach whether these peptides bind to MDP or are "MDP-binding homing molecules." Thus, while the specification discloses two peptides with a GFE motif which home to lung endothelium and bind MDP, the art teaches two peptides with a GFE motif which appear to "home" to a different tissue and

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are NOT known to bind MDP, thus showing the degree of uncertainty in the art over whether a peptide of SEQ ID NO: 17 would be expected to be an MDP-binding homing molecule which binds selectively to lung endothelium.

The level of skill in the art is acknowledged to be high. However, given the lack of teaching in the specification or the prior art for any peptides other than SEQ ID NO: 1 or SEQ ID NO:2 which home to MDP and selectively bind lung endothelium, and the degree of uncertainty in the art over whether the genus of GFE peptides represented by SEQ ID NO: 17 are necessarily those which are MDP-binding homing molecules and bind selectively to lung endothelium, it would require undue experimentation by one skilled in the art to determine how to successfully perform the method of claims 5 and 6 with any peptide other than SEQ ID NO: 1 or SEQ ID NO: 2. For these reasons, claims 5 and 6 are enabled for use of SEQ ID NO's 1 and 2, but not for use of any other peptide represented by SEQ ID NO: 17.

### ***Claim Objections***

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for improperly limiting a parent claim. Claim 5 depends from claim 1, which is cancelled. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. For purposes of search and further examination, claim 5 will be interpreted as if it recited a method of selectively directing a moiety to lung endothelium in a subject comprising administering to the subject a conjugate comprising a moiety linked to an MDP-homing

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molecule, whereby said moiety is selectively directed to lung endothelium in said subject.

Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Allowable Subject Matter***

The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or fairly suggest a method of selectively directing a moiety to lung endothelium wherein the moiety is conjugated to either SEQ ID NO's 1 or SEQ ID NO: 2.

### ***Conclusion***

Claims 5-6 are rejected; claims 5 and 7 and the specification are objected to. Claim 7 is free of the prior art. Claims 8-30 are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone

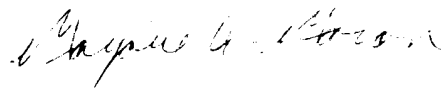


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numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN  
PATENT EXAMINER



mam  
June 14, 2003